TECHNICAL SERVICES MONTHLY REPORT

Nov 2022 to July 2023

TSD Approach

- **Service Capabilities**
  - On time deliverables
  - Quality Work
- **Trouble Shooting**
  - Unit Process
  - Unit Operations
- **Continuous Improvements**
  - Solvent
  - Yield
  - Capacity
- **New Products**
  - Eqp. Mapping
  - Trail & Validation
  - Execution

Ongoing Projects

- Capacity Enhancement
- New Products
- Technical Support
- New Proposals

Capacity Enhancement

Product Name: Pregabalin

Stage Code :

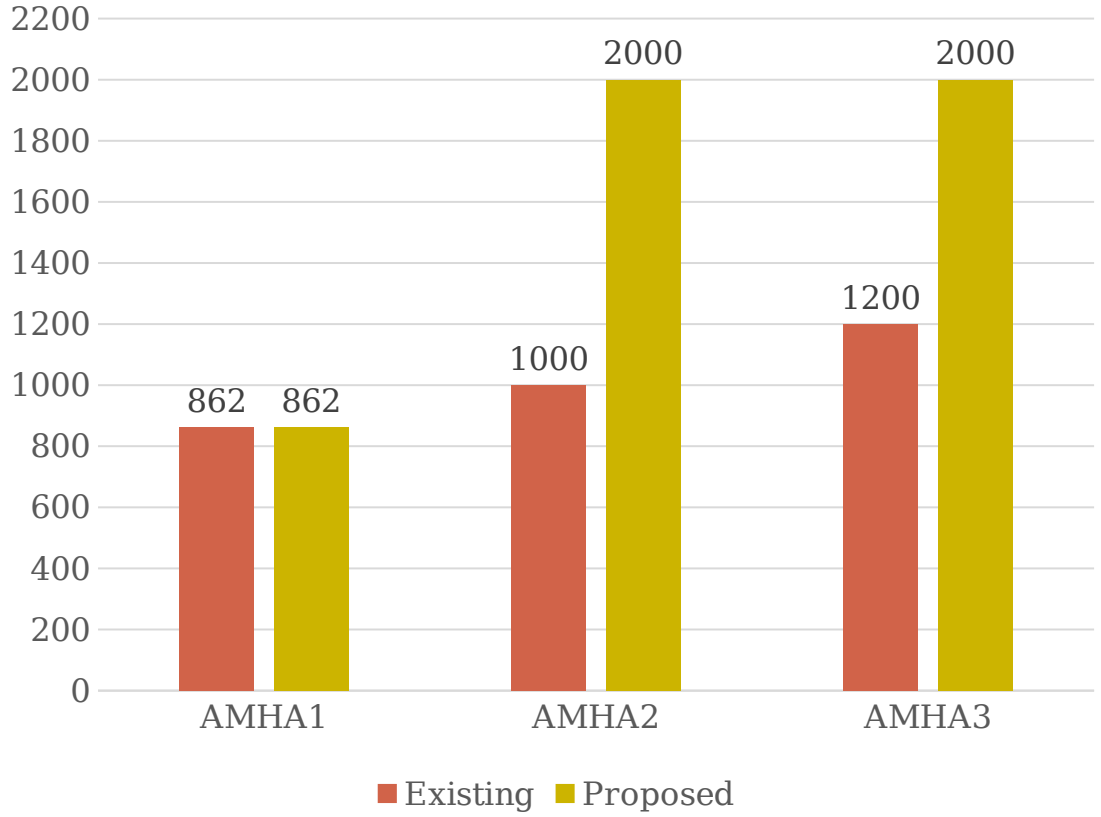
AMHA1: Additional streams included, **AMHA2:** Scale-up from 1000 Kg in A-Block to 2000 Kg in C-Block & **AMHA3:** Additional streams included.

Block: A, B & C.

Existing : 18 to 20 TPM.

Proposed : 28 to 30 TPM.

AMHA1		AMHA2		AMHA3	
Existing	Proposed	Existing	Proposed	Existing	Proposed
862 kg	862 kg	1000 kg	2000 kg	1200 kg	2000 kg



Capacity Enhancement

Product Name: Atorvastatin Calcium

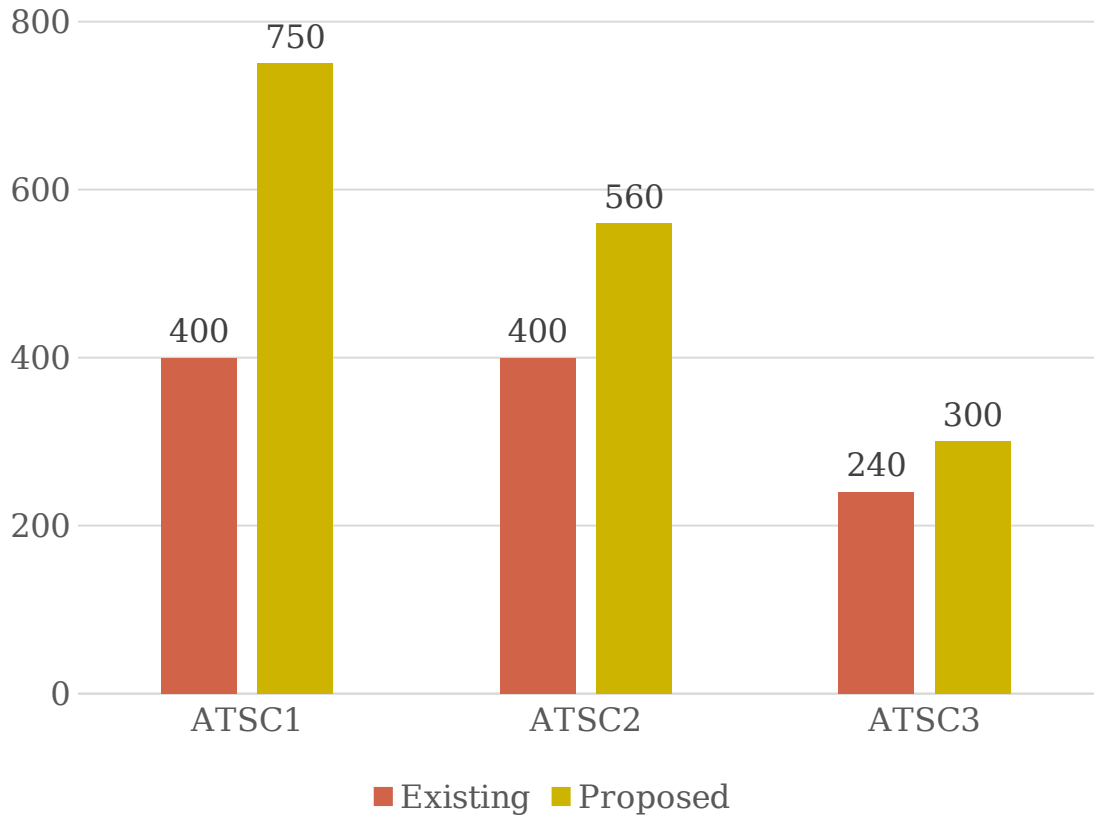
Stage Code : ATSC1, ATSC2 & ATSC3.

Block: B & E.

Existing : ~4.2 TPM.

Proposed : ~8.4 TPM.

ATSC1		ATSC2		ATSC3	
Existing	Proposed	Existing	Proposed	Existing	Proposed
400 kg	750 kg	400 kg	560 kg	240 kg	300 kg



Capacity Enhancement

Product Name:
Rosuvastatin Calcium (RA)

Stage Code : RVST1 & RVST2.

Block: E & B.

Existing : 1.7 TPM.

Proposed : 4.0 TPM.

RVST1		RVST2	
Existing	Proposed	Existing Phase-I	Proposed Phase-II
150 kg	350 kg	125 kg	300 kg

Capacity Enhancement

Product Name:
Ranolazine

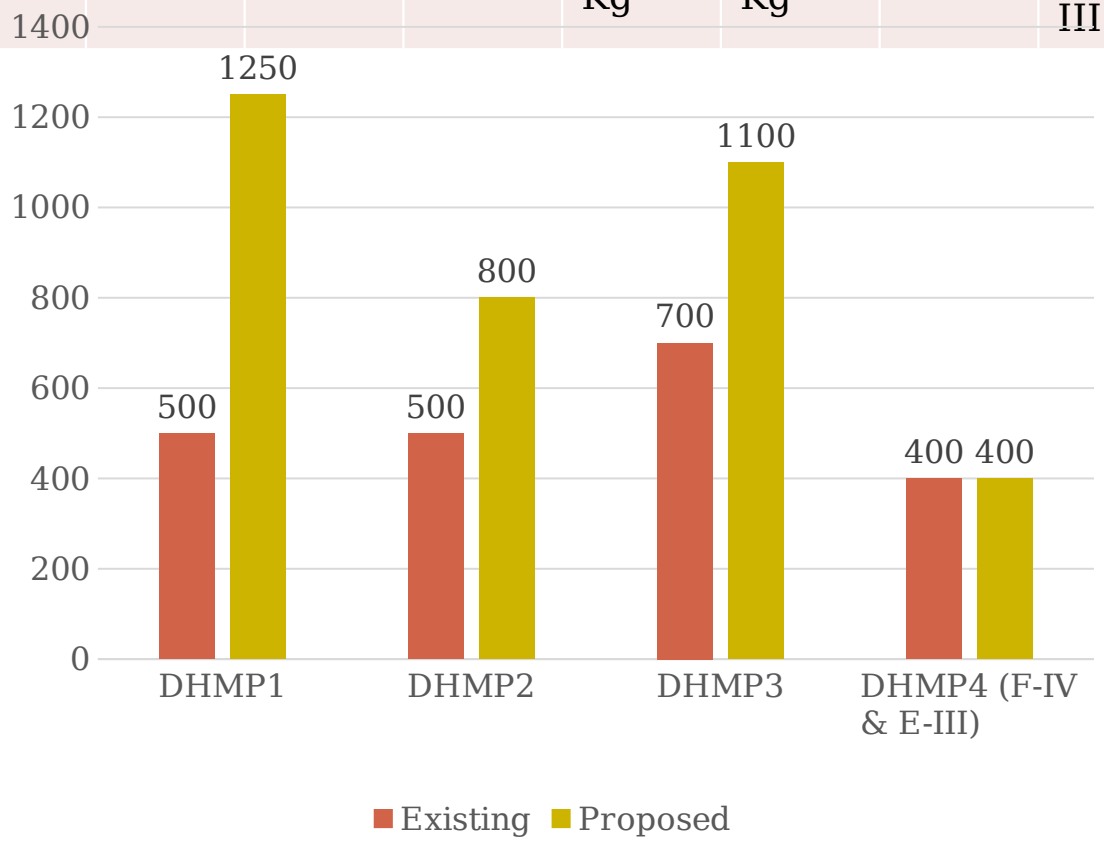
Stage Code : DHMP1 , DHMP2, DHMP3 & DHMP4.

Block: B, C & E-III.

Existing : ~ 8.0 TPM.

Proposed : ~ 16.0 TPM.

DHMP1		DHMP2		DHMP3		DHMP4	
Existing	Proposed	Existing	Proposed	Existing	Proposed	Existing	Proposed
500 Kg	1250 Kg	500 Kg	800 Kg	700 Kg	1100 Kg	F-IV	F-IV & E-III



Capacity Enhancement

Product Name: Levetiracetam (Doc)

Stage Code : LVTC1 & LVTC2.

Block: B and E-IV&F-IV.

Existing : ~ 8 TPM.

Proposed : ~ 40 TPM.

LVTC1		LVTC2	
Existing	Proposed	Existing	Proposed
400 Kg	800 Kg	450 Kg	800 Kg

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

SUCRALFATE

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
SFTE1	T1	26-10-22	31-10-22	7.0	20.36	17.58 to 21.48
SFTE1	V1	19-11-22	23-11-22	7.4	23.2	18.59 to 22.71
SFTE1	V2	07-12-22	11-11-22	7.4	24.18	
SFTE1	V3	20-12-	25-12-	7.4	24.5	

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
SFTE2	T1	15-12-22	21-01-23	20	34.55	31.80 to 38.8
SFTE2	V1	02-01-23	08-01-23	22	39.2	34.98 to 42.68
SFTE2	V2	11-01-23	17-01-23	22	35.2	
SFTE2	V3	18-01-23	24-01-23	22	37.1	

New Products

New Products

Sucralfate

PSD as per Customer requirement
D90 NMT : 15(µm)

SSA NLT : 4.

Micronization three times trails done and meet the customer requirement.

SUCRALFATE MICRONIZATION DETAILS

Batch No	I/p (Kg)	O/p (Kg)	Top Sieved (Kg)	Loss Qty (Kg)	Samples Qty (Kg)
PSCFT 0051222	14	11.2	1.2	1.28	0.32
PSCFT 006122	12.9	11.39	0.23	1.055	0.195

Trail	D90 (µm)	D50 (µm)	D10 (µm)	SSA
Plain material	399	168	38.5	---
1st time Micronization	22.2	9.48	2.57	2.848
2nd Time Micronization	13.9	6.5	2.12	5.777
3rd Time Micronizatio	12	5.92	1.89	5.873

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

ISTRADEFYLLIN E

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
IDLE1	T1	03-12-22	03-12-22	7.00	8.00	6.44 to 7.98
IDLE1	V1	20-12-22	23-12-22	7.50	7.69	
IDLE1	V2	28-12-22	31-12-22	7.50	8.94	6.90 to 8.5

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
IDLE2	T1	27-01-23	01-02-23	7.50	8.64	7.95 to 9.75
IDLE2	T1 (RP)	04-03-23	05-03-23	8.00	6.78	6.23 to 7.76
IDLE2	V1	22-03-23	04-04-23	7.50	7.78	
IDLE2	V2	07-04-23	14-04-23	7.50	6.04	5.50 to 8.50
IDLE2	V3	14-04-23	22-04-23	7.50	7.90	

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

E

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
IDLE3	T1	14-04-23	17-04-23	6.50	5.12	5.07 to 6.18
IDLE3	V1	25-04-23	28-04-23	7.00	6.00	4.41 to 6.62
IDLE3	V2	04-05-23	06-05-23	7.00	5.70	
		07-05	10-05			

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
IDLE4	T1	26-04-23	29-04-23	5.00	4.26	3.95 to 4.83
IDLE4	V1	16-05-23	19-05-23	5.50	5.00	4.35 to 5.31
IDLE4	V2	24-05-23	27-05-23	5.50	5.10	
IDLE4	V3	01-06-23	03-06-23	5.50	5.10	

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

VOXELOTOR

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
VOTR 1	T1	02-11-22	06-11-22	40	67.9	59.2 to 72.4
VOTR 1	V1	29-11-22	02-12-22	42	71.1	
VOTR 1	V2	08-12-22	12-12-22	42	72.1	62.16 to 76.02

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
VOTR 2	T1	24-11-22	28-11-22	10	9.8	8.2 to 10.0
VOTR 2	T2	06-12-22	16-12-22	57	46.3	46.74 to 57
VOTR 2	RP	--	19-02-23	25.45	18.82	---
VOTR 2	V1	06-01-23	12-01-23	70	66.6	
VOTR 2	V2	13-01-23	22-01-23	70	66.0	57.4 to 70.0
VOTR		20-01-	29-01-			

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

VOXELOTOR

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
VOTR 3	T1	07-01-23	12-01-23	45	39.5	34.65 to 42.3
VOTR 3	RP	--	--	39.5	34.7	--
VOTR 3	V1	23-02-23	04-03-23	63	57.54	48.51 to 59.23
VOTR 3	V2	02-03-23	13-03-23	63	57.50	
VOTR 3	V3	07-03-23	17-03-23	63	57.30	

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

RIMEGEPANT

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
RMGS 1	V2	07-04-23	15-04-23	310	221.51	226.92 to 277.35
RMGS 1	V3	14-04-23	23-04-23	310	221.20	

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
RMGS 2	V1	09-04-23	15-04-23	255	201.08	170.70 to 206.37
RMGS 2	V2	18-04-23	24-04-23	255	183.19	
RMGS 2	V3	25-04-23	02-05-23	247	163.45	
RMGS 2	V3 (Lot-1 RP)	20-05-23	21-05-23	91.5	69.95	--

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

RIMEGEPANT

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
RMGS 3	V1	18-04-23	27-04-23	130	75.47	70.20 to 85.80
RMGS 3	V2	28-04-23	07-05-23	230	129.7	124.20 to 151.80
RMGS	V3	26-05-	03-06-	189	101.4	102.06 to

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
RMGS 4	V1	29-04-23	08-05-23	125	102.24	85.00 to 103.75
RMGS 4	V2	12-05-23	22-05-23	125	119.7	
RMGS 4	V3	08-06-23	18-06-23	129.3	118.4	87.92 to 107.32

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

Sitagliptin (Enzyme Route)

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
SATM1	T1	08-06-23	13-06-23	100	122.43	105.00 to 129.00
SATM1	T2	21-06-23	26-06-23	450	601.16	472.52 to 580.48
SATM1	V1	07-07-23	13-07-23	450	595.73	540.90 to 613.04
SATM1	V2	11-07-23	17-07-23	450	591.28	
SATM1	V3	16-07-23	22-07-23	450	598.32	

New Products

New Products

Sucralfate

Istradefylline

Voxelotor

Rimegepant

Sitagliptin (Enzyme Route)

Sitagliptin (Enzyme Route)

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
SATM2	T1	17-06-23	23-06-23	122	144.2	145.18 to 176.90
SATM2	T2	03-07-23	12-07-23	550	649.1	654.50 to 797.50
SATM2	V1	20-07-23	26-07-23	550	666.48	584.65 to

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
SATM3	T1	10-07-23	16-07-23	143	93.74	105.82 to 130.13
SATM3	T2	26-07-23		450		333.00 to 409.50

TECHNICAL SUPPORT

Equipment Mapping & Facility Creation:

- 6.0 KL Hydrogenation Reactor facility created in B-Block for ATSC1 stage of Atorvastatin calcium and scale-up batches execution completed with Input 400 Kg, 600 Kg & 750 Kg.
- Azeotropic Set-up arranged for Oseltamivir Phosphate for water removal.
- Vacuum balancing set-up arranged to F/SSR/03 (4 KL) in F-Block for Rosuvastatin Calcium Pharma Stage.
- Vildagliptin Stage-1 Modified process Execution at 40 Kg Scale completed. Scale-up to be executed after receiving new 1.0 KL Halar Lined PNF.
- Rosuvastatin Ca. Single stage process for IP-Execution completed with 75 Kg Batch Size, Scale-up to be planned.
- Additional streams in Pregabalin RM route for capacity enhancement from 4.5 TPM to 10 TPM.
- MDC Solvent Recovery improved in Pantaprazole by implementing brine circulation for Primary condenser.

TECHNICAL SUPPORT

Troubleshooting:

- Flecainide Acetate required PSD (D50- NLT 5 µ) achieved by
  1) Agitator RPM Reduced from 96 to 60 Rpm
  2) Acetic acid solution with 2 vol. instead of 1 vol toluene.
  3) Acetic Acid Addition Time Increased To 60-90 Min.
  4) Toluene slurry in ANFD
- Pregabalin Flowability requirement for M/S Zentiva- Sifting Trials u/process to achieve desired nature.

New Production Blocks:

- I-Block equipment's i.e., Filtration and Drying equipment's modified as per Mr. Vithal sir instruction.
- Accessories requirements finalized for G-Block & D-Blocks.

New Proposal

- Experiments conducted for Hydrolysis Reaction to avoid frothing and to increase batch size in PREGABALIN (AMHA1) in heating condition. Process Finalized with Reverse addition at 70-75°C & Scale-up batches upto 500 Kg B.Size executed in Plant.
- ANFD Filtration & Drying trail conducted to reduce the drying time cycle in Atorvastatin Calcium (ATSC3), slow filtration and hard lumps observed.
- RCVD trail for Atorvastatin Calcium (ATSC3) for drying to be plan.
- Homogenizer trails planning for Atorvastatin Calcium.
- Flow Chemistry Experiment Trials conducted for Enzyme Reaction & Amidation reaction of Pregabalin Stage-2.

MSN
LIFE SCIENCES-III
Bhiknoor.